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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/786,937	01/22/1997	PHILIPPE BOUCHARD	098501-0235299	5859

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EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
10/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/786,937	BOUCHARD ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38, 39, 42, 44-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 38,39,42,44-51,56-63,65,67-70,72-75,78-80,83,84,86-92,94-100,102-105,107,108,110-116,118,119,121-123 and 126-141.

DETAILED ACTION

Response to Amendment

The amendment filed 20 August 2008 is acknowledged. Claims 38 and 51 are currently amended. The amendment filed 15 November 2007 is acknowledged. Claims 38 and 51 are currently amended. Claims 38, 39, 42, 44-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, and 126-141 are under examination.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. 102(b) as being anticipated by Diedrich et al. (cited in previous Office actions, mailed 13 September 2006, 15 May 2007 and 20 February 2008) is maintained for reasons of record and the following.

Applicants argue at p. 15, last 2 paragraphs that claims 38 and 51 are amended to specify that the methods "consist essentially of", thus the claims do not encompass Diedrich et al.

This argument has been fully considered but is not found persuasive. The reasons are outlined in the Examiner's comment immediately below.

Applicants argue at p. 16, 2nd paragraph that Diedrich et al. teach a suppression of FSH under Cetrorelix administration.

The Examiner takes no issue (and took no issue) with the statement that Diedrich et al. teach a suppression of FSH under Cetrorelix administration, but rather, the issue is that the recited method steps do not distinguish over the prior art. First, the claim amendments recite “remains the same throughout the treatment period”, however, the treatment period is never defined in the steps. Second, in claim 38 part (a), it states "wherein the dose of LH and FSH remains the same" and in claim 51, part (a) it states “wherein the dose of hMG remains the same", but it is not clear what this means. Is a pump used to maintain the same level of LH/FSH and/or hMG over several hours or days? Claim 38 part (b) and claim 51 part (b) state “single or dual dosage”, but does that mean two separate doses that add up to a total of 3mg or do two separate 3mg doses? In other words, in spite of the addition of “consisting essentially of”, the claim language is not distinguished over the art because the claim language is sufficiently vague to allow for additional steps.

Regarding the limitation that FSH be "maintained at a natural level", given that the treatment period is undefined, this requirement does not limit the steps. At what point during the treatment period is the endogenous FSH secretion not suppressed? Specifically, note that Diedrich et al. teach at p. 790, left column, 3rd paragraph that

"only in the ***luteal phase*** was a decrease in FSH seen." The luteal phase spans from ovulation at about midcycle until menstruation, so given that the treatment period in the amended claims is undefined, it is not clear when in the instant method steps FSH must be maintained at its natural level. It can be reasonably interpreted that a "treatment period" lasts until ovulation occurs since the goal of the method steps is to achieve a fertilizable oocyte. According to the statement at p. 790 of Diedrich et al., it can also be reasonably concluded that if FSH decreased only during the luteal phase, then it was maintained at a natural level prior to that. If the patient following the protocol described in Diedrich et al. ovulates on day 14 of the menstrual cycle, and a fertilizable oocyte is produced, then the decrease in FSH observed by Diedrich and colleagues occurred outside the "treatment period". In short, the claim limitations do not clearly define the treatment period, thus the added limitation requiring that FSH be maintained at a natural level does clearly distinguish over Diedrich et al.

Applicants argue at p. 17, 1st paragraph that the Examiner misplaces emphasis on the disclosure in Albano et al. that the maintenance of FSH levels may be associated with the lower does of antagonist used or possibly to the influence of the exogenous FSH and alleges that the art does not distinguish between added and endogenous FSH. Applicants further draw attention to the dose of LHRH antagonist used in Albano et al., which is approximately one sixth of the does of Diedrich et al., and conclude that since both studies used exogenous FSH, any difference in FSH levels observed must be due to endogenous FSH levels.

This argument has been fully considered but is not found persuasive. First, the reference to the dose of antagonist used by Albano et al. is misplaced since the claims recite 3 mg, not 0.5 mg of LHRH antagonist, and no rejection was made over Albano et al. Second, at p. 2117, left column, 1st paragraph Albano et al. state, "[in] our study the FSH concentration increased after hMG administration, coinciding with the blood

samples taken in the afternoon. Indeed the blood sample obtained in the morning before the hMG injection showed a decrease in FSH concentration, which was probably due to the plasma half-life of exogenous FSH." This statement in Albano et al. does not support Applicants' argument that "any difference in FSH levels observed must be due to endogenous FSH levels", but rather seems to suggest that FSH levels increased after exogenous administration and decreased prior to administration due to plasma half-life. Finally, Applicants have not addressed the Examiner's concern with regard to Felberbaum et al., cited in the previous Office action mailed 20 February 2008, where it stated that "Felberbaum et al. (Human Reprod. 1999; 14: 207-21—cited in previous Office action mailed 20 February 2008) teach at p. 210 that in response to a protocol administering 3, 1, 0.5 or 0.25 mg Cetrorelix/day, little suppression of FSH was observed "mainly due to the fact that ***exogenous*** FSH [emphasis added], which has a distinctly longer half-life in comparison to LH had been constantly administered during ovarian stimulation." Again, this does not support Applicants' argument that any differences are due to exogenous FSH levels. In short, the phrase "does not suppress endogenous FSH secretion, which in maintained at a natural level" does not distinguish over the prior art.

Applicants argue at p. 17, 2nd paragraph that one of skill in the art was aware that the methods taught by Diedrich et al. caused a suppression of both LH and FSH and thus the amended claims are not anticipated by Diedrich et al.

This argument has been fully considered, but is not found persuasive. In summary, given the comments above that the treatment period is undefined, at what point during this undefined treatment period is the endogenous FSH secretion not

suppressed? Specifically, note that Diedrich et al. teach at p. 790, left column, 3rd paragraph that "only in the ***luteal phase*** was a decrease in FSH seen." The luteal phase spans from ovulation at about midcycle until menstruation, so given that the treatment period in the amended claims is undefined, it is not clear when in the instant method steps FSH must be maintained at its natural level. It can be reasonably interpreted that a "treatment period" lasts until ovulation occurs, since obtaining a fertilizable oocyte is the goal of the claims. According to the statement at p. 790 of Diedrich et al., it can also be reasonably concluded that if FSH decreased only during the luteal phase, then it was maintained at a natural level prior to that. If the patient following the protocol described in Diedrich et al. ovulates on day 14 of the menstrual cycle, and a fertilizable oocyte is produced, then the decrease in FSH observed by Diedrich and colleagues occurred outside the "treatment period". In short, the claim limitations do not clearly define the treatment period, nor when endogenous FSH is maintained, thus do not clearly distinguish over Diedrich et al.

The rejection of claims 38, 39, 42, 44-46, 48-51, 56-58 and 60 under 35 U.S.C. 102(a) as being anticipated by Olivennes et al. (Human Reprod. 1995; 10: 1382-1386) as set forth in the previous Office action mailed 20 February 2008 is maintained for reasons of record and the following.

Applicants argue at p. 18, 2nd paragraph that Olivennes et al. disclose that hMG was increased on the day the Cetrorelix was administered," thus does not teach every element of the claim.

This argument has been fully considered but is not found persuasive. Claim 38 part (a), states "wherein the dose of LH and FSH remains the same" and claim 51, part (a) states "wherein the dose of hMG remains the same", but the meaning is not clear. Is a pump used to maintain the same level of LH/FSH and/or hMG over several hours or days? Second, the "treatment period is undefined. In other words, in spite of the addition of "consisting essentially of", it is not clear enough from the claim language what the steps are, thus an increase in hMG is encompassed by the claimed methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

It is noted that Application No. 10/661,780 has been patented, (U.S. Patent 7,393,834), thus this rejection is no longer provisional, and Applicants' argument at p.

19, 2nd paragraph that the provisional double patenting rejection must be withdrawn without a terminal disclaimer when it is the only rejection remaining is not persuasive. First, it is not the only rejection remaining. Second, it is no longer provisional. Thus the rejection of claims 38-39, 42, 45-51, 56-63, 65, 67-70, 72-75, 78-80, 83, 84, 86-92, 94-100, 102-105, 107, 108, 110-116, 118, 119, 121-123, 126-141 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the now patented claims of copending Application No. 10/661,780 22, 26-42 is maintained for reasons of record.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is (571)272-4482. The examiner can normally be reached on 8:00am - 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646